

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Pu Zhou	Confirmation No.:	9310
Serial No.:	10/615,651	Examiner:	Monica A. Huson
Filing Date:	July 9, 2003	Group Art Unit:	1732
Docket No.:	1001.1662101	Customer No.:	28075
For:	METHOD OF FORMING CATHETER DISTAL TIP		

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By



Kathleen L. Bookley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on December 22, 2006, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed January 29, 2007. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$500.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation. Appellant hereby appeals the rejection of claims 1-11, 13-14, and 35-41 of the above-captioned application.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a subsidiary of Boston Scientific Incorporated, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Pu Zhou, conveying all right, title and interest in the invention to Scimed Life Systems, Inc. has been recorded at Reel 014272, Frame 0499. A Change of Name from Scimed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known prior and pending appeals, judicial proceedings or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-11, 13, 14 and 35-41 are pending in the application; claims 1-11, 13 and 35-41 have been rejected, and claim 14 has been withdrawn from consideration. Claims 12 and 15-35 have been cancelled.

Claims 1, 11, 13 and 35-41 stand finally rejected under 35 U.S.C. § 102(e) as being anticipated by Noone et al. (U.S. Patent No. 6,591,472).

Claims 2-5, 7 and 9-10 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Noone et al. in view of Wilson (U.S. Patent No. 5,951,929).

Claim 6 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Noone et al. in view of Wilson, further in view of Zadno-Azizi (U.S. Publication No. 2004/0015150).

Claim 8 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Noone et al. in view of Ashiya et al. (U.S. Patent No. 5,947,925).

The rejection of claims 1-11, 13 and 35-41 of the application is the subject of the current appeal.

IV. STATUS OF AMENDMENTS

A Response After Final was filed on September 29, 2006 in which no claim amendments were made, but all pending claims, including updated status identifiers, were presented in a clean version along with accompanying remarks requesting reconsideration in response to a Final Office Action mailed August 2, 2006. An Advisory Action was mailed on October 23, 2006 stating that the request for reconsideration was considered but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The invention relates generally to methods for forming a catheter that can include a reinforcing braid layer and can also include an atraumatic distal tip in which the reinforcing braid layer does not extend into the distal tip. (1:18-20)²

Turning now to the claims, claim 1 is an independent claim, which is directed to a method of forming a catheter (10:16-17), comprising providing a braid layer (48) having a distal end and a proximal end, an inner lubricious liner (44) positioned within the braid layer (10:17-20; Figs. 5 & 6), securing a first polymer segment (50) over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end (11:1-4; Fig. 7), cutting through the braid layer and the inner lubricious liner at a cutting position (60) proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position (13:8-14; Fig. 10), and subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment (62) over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position (13:15-14:6; Fig. 11).

Claim 2, which depends from claim 1, further recites wherein the first polymer segment (50) has a melting point that is at least about 10° F above a melting point of the second polymer segment (62) (11:10-15; 14:7-13).

¹ The references to the specification and drawings provided herein are exemplary and are not intended to be limiting.

² All references in this section are to the specification of the application under appeal. Any reference in this form is to the page number and then to the line numbers. For example, this reference is to page 1, lines 18-20.

Claim 3, which depends from claim 1, further recites wherein securing the first polymer (50) segment comprises positioning a heat shrink tube (58) over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment (12:12-19).

Claim 4, which depends from claim 1, further recites wherein securing the second polymer segment comprises positioning a heat shrink tube (70) over the second polymer segment (62) and applying sufficient heat and pressure to melt the second polymer segment (62) but not enough heat to melt the first polymer segment (50) (14:14-19).

Claim 5, which depends from claim 4, further recites wherein the first polymer segment (50) has a melting point that is greater than about 400° F and the second polymer segment (62) has a melting point that is less than about 400° F(11:10-15; 14:7-13).

Claim 6, which depends from claim 4, further recites wherein the second polymer segment (62) has a melting point that is about 350° F (14:10-12).

Claim 7, which depends from claim 1, further recites wherein the first polymer segment (50) comprises a polyether-ester elastomer (11:12-14).

Claim 8, which depends from claim 1, further recites wherein the second polymer segment (62) comprises a acetal resin/polyurethane blend (14:10-12).

Claim 9, which depends from claim 3, further recites wherein the heat shrink tube (58) comprises a perfluoro (ethylene-propylene) copolymer (12:22-13:2).

Claim 10, which depends from claim 4, further recites wherein the heat shrink tube (70) comprises a perfluoro (ethylene-propylene) copolymer (14:22-23; 12:22-13:2).

Claim 11, which depends from claim 1, further recites wherein the second polymer segment (62) comprises in combination a proximal segment (64) configured to overlay the braid layer, an intermediate segment (66) configured to overlay the first polymer segment, and a distal segment (68) configured to form a distal tip (13:22-14:6, Fig. 11).

Claim 13, which depends from claim 1, further recites wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position (11:20-12:11, Figs. 9 & 10).

Claim 35 is an independent claim directed to a method of forming a catheter, comprising cutting a catheter sub-assembly at a cutting location (60), the sub-assembly having proximal and

distal ends, an inner layer (44), a reinforcement layer (48) disposed on the inner layer (44), and a securement layer (50) disposed over at least a portion of the reinforcement layer (10:16-11:4), removing the inner layer (44), the reinforcement layer (48), and the securement layer (50) distally of the cutting location (13:8-14); and subsequent to removing the inner layer (44), the reinforcement layer (48), and the securement layer (50) distally of the cutting location, securing a polymeric outer segment (62) over at least the securement layer (50) such that a portion of the polymeric outer segment (62) extends distally of the cutting location (60) (13:15-21).

Claim 36, which depends from claim 35, further recites forming a portion of the polymeric outer segment (62) into a distal tip for the catheter (13:22-14:6).

Claim 37, which depends from claim 35, further recites assembling the catheter sub-assembly by providing an inner sub-assembly having the reinforcement layer (48) disposed on the inner layer (44); and disposing the securement layer (50) on the inner sub-assembly by securing a securement segment thereon (11:1-4).

Claim 38, which depends from claim 37, further recites wherein the reinforcement layer (48) has a distal end; the securement segment has a distal end; and the step of disposing the securement layer (50) on the inner sub-assembly is performed such that the distal end of the reinforcement layer (48) extends distally beyond the distal end of the securement segment (11:20-12:5).

Claim 39, which depends from claim 35, further recites wherein the reinforcement layer (48) comprises a braided member (10:19-20).

Claim 40 is an independent claim directed to a method of forming a catheter, comprising providing a braid layer (48) having a distal end and a proximal end (10:19-20); positioning an inner lubricious liner (44) within the braid layer (10:14-19); securing a first polymer segment (50) over the braid layer (48), the first polymer segment (50) being positioned proximal of the distal end of the braid layer (48) (11:1-4); cutting through the braid layer (48) at a cutting location (60) proximal of the distal end of the braid layer (48), thereby forming a catheter sub-assembly including the inner lubricious liner (44), the braid layer (48), and the first polymer segment (50), the catheter sub-assembly having a distal end defined at the cutting location (60) (13:8-14); and securing a second polymer segment (62) over the catheter sub-assembly, the second polymer

segment (62) extending over the first polymer segment (50) of the catheter sub-assembly and extending distally of the distal end of the catheter sub-assembly; wherein the step of securing the second polymer segment (62) over the catheter sub-assembly is performed subsequent to the step of cutting through the braid layer (13:8-14).

Claim 41, which depends from claim 40, further recites wherein the first polymer segment (50) prevents flaring of the braid layer (48) consequent cutting through the braid layer (13:3-7).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

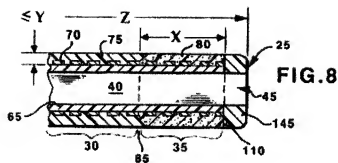
1. *Whether claims 1, 11, 13 and 35-41 are anticipated by Noone et al. (U.S. Patent No. 6,591,472) under 35 U.S.C. § 102(e).*
2. *Whether claims 2-5, 7 and 9-10 are unpatentable over Noone et al. in view of Wilson (U.S. Patent No. 5,951,929) under 35 U.S.C. § 103(a).*
3. *Whether claim 6 is unpatentable over Noone et al. in view of Wilson, further in view of Zadno-Azizi (U.S. Publication No. 2004/0015150) under 35 U.S.C. § 103(a).*
4. *Whether claim 8 is unpatentable over Noone et al. in view of Ashiya et al. (U.S. Patent No. 5,947,925) under 35 U.S.C. § 103(a).*

VII. ARGUMENT

- A. *Claims 1, 11, 13 and 35-41 are not anticipated by Noone et al. (U.S. Patent No. 6,591,472) under 35 U.S.C. § 102(e)*

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 recites “subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position.” Noone et al. do not teach securing a second polymer segment over a braid layer subsequent to cutting through the braid layer and the inner lubricious liner as claimed. Therefore, Noone et al. do not anticipate independent claim 1.

The rejection in the Final Office Action is based on Figure 8 and corresponding portions of the specification. Figure 8 of Noone et al. is reproduced below:



Referring to Figure 8, Noone et al. state:

FIG. 8 is a partial cross-section view of a distal catheter body end formed in accordance with the fabrication steps of FIGS. 1 and 2 and having a discrete distal soft tip 45 attached thereto in the final fabrication step S212. The discrete distal soft tip 145 can also be formed at the distal catheter body end 25 of the other embodiments of the invention described hereinafter. The distal soft tip 145 can be formed with radiopaque material encased therein and can be shaped and attached to form the distal catheter body end 25 in a manner disclosed in the above-referenced '910 patent to Lunn or the '149 patent to Brin et al. or in the above-referenced copending '241 patent application. (Column 12, lines 52-63.)

In formulating the rejection, the Examiner apparently equates the distal soft tip 45, 145 taught in Noone et al. with the second polymer segment currently claimed in claim 1. Appellant respectfully disagrees. The distal soft tip 45, 145 is abutted to the catheter shaft at reference numeral 110. Thus, as shown in Figure 8, no portion of the distal soft tip 45, 145 (which is a discrete member as evidenced at line 54 of column 12) extends over another polymer segment. This is evidenced by the fact that various components of the catheter are represented by various cross-hatchings. All other components of the catheter end at the dashed lines at reference numeral 110 and no other component of the catheter disclosed at Figure 8 extend into the portion of the catheter defined by the distal soft tip 45, 145. Thus, no portion of the distal tip disclosed in Figure 8 of Noone et al. extends over another portion of the catheter as currently claimed.

The question of whether tip 45 of Noone et al., which abuts the reinforcing layer 70, can be said to be secured over the reinforcing layer (which must be the case if Noone et al. anticipate the claim) is central to whether Noone et al. anticipate the claims. Appellants respectfully contend Noone et al. do not anticipate the claims because an interpretation of the language of claim 1 "securing a second polymer segment over the braid layer, the second polymer segment extending

over the first polymer segment and extending distally of the cutting position” that can be read to include such an abutting configuration as described in Noone et al. is impermissibly broad.

While the Examiner has a duty to give the pending claims their broadest reasonable interpretation, that interpretation must be reasonable and “must also be consistent with the interpretation that those skilled in the art would reach.” MPEP 2111 citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). No one of skill in the art would reasonably reach an interpretation of this language that includes the abutting configuration disclosed in Noone et al.

In the Advisory Action of October 23, 2006, the Examiner responded to Appellant’s arguments by writing “applicant contends that Noone does not show securing a polymeric outer segment over the securement layer or the first polymer section. This is not persuasive because the outer polymeric segment is secured over the end of the two said layers.”

The Examiner appears to confuse what “over” means; placing a first thing to cover a surface of a second does not necessarily mean that the first thing is over the second. Appellants would suggest that the configuration described by Noone et al. is a design where the element merely covers a side surface of the other. “Over” is a preposition that implies a direction, and when used with respect to an object such as a catheter, which can be twisted and moved so that any end or side might be up, the direction is understood by those of skill in the art to be in reference to the elongate central axis of the catheter. If a second layer is said to be over a first layer, the second layer is understood to be at the same position along the axis as the first layer but further out radially. This is the interpretation that those of skill in the art reach absent some teaching to the contrary in the specification. Thus when claim 1 recites “the second polymer segment extending over the first polymer segment and extending distally of the cutting position,” the claim is not being redundant. A segment cannot extend over another segment solely by extending distally of that other segment. The claim language requires that the segment be at the same position along the axis of the catheter and further out radially.

Noone et al. do not disclose such a configuration. As can be seen in Figure 8, distal tip 45 abuts against the reinforcing layer and the first polymer segment but is not disposed or secured over either of them. It can therefore be seen that Noone et al. do not teach each and every claim element. For at least this reason, Appellant submits that claim 1 is not anticipated by Noone et al.

Claim 11 further recites “wherein the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip.” To show anticipation, the Examiner argued that elements 75 and 145 make up this second polymer section. Final Office Action of August 2, 2006, page 3. However, element 75 is a proximal outer layer “which is formed by final layer 115.” 12:41-42. This final layer 115 is extruded onto the catheter prior to cutting through the braid layer. 11:58-60 & 12:9-11. Thus layer 75 cannot be part of a second polymer segment, which is secured to the catheter “subsequent to cutting through the braid layer.” Because claim 11 depends from claim 1 and contains additional elements, as well as for this additional reason, Appellant submits that claim 11 is not anticipated by Noone et al.

Claim 13 depends from claim 1 and contains additional elements; for at least this reason, Appellant submits that this claim is not anticipated by Noone et al.

Claim 35 recites “subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment extends distally of the cutting location.” Therefore, for at least the reasons discussed above with respect to claim 1, Appellant submits that claim 35 is not anticipated by Noone et al.

Claims 36-39 depend from claim 35 and contain additional elements; for at least this reason Appellant submits that these claims are also not anticipated by Noone et al.

Claim 40 recites “wherein the step of securing the second polymer segment over the catheter sub-assembly is performed subsequent to the step of cutting through the braid layer.” Therefore, for at least the reasons discussed above with respect to claim 1, Appellant submits that claim 40 is not anticipated by Noone et al.

Claim 41 depends from claim 40 and contains additional elements. For at least this reason, Appellant submits that claim 41 is not anticipated by Noone et al.

B. *Claims 2-5, 7 and 9-10 are patentable over Noone et al. in view of Wilson (U.S. Patent No. 5,951,929) under 35 U.S.C. § 103(a)*

1. *The prior art references must suggest the desirability of the claimed invention*

To establish *prima facie* obviousness of a claimed invention, “it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitute, combination, or other modification.” *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Claim 2 recites “wherein the first polymer segment has a melting point that is at least about 10° F above a melting point of the second polymer segment.” The Examiner argues in the Final Office Action of August 2, 2006 that “it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Wilson’s material during Noone’s method in order that the first polymer segment will not remelt upon application of the second polymer segment.” Page 6. However, the second polymer segment of Noone et al. is the distal tip 45. Noone et al. teach that the tip is joined to the catheter body in a manner well known in the art, but is silent as to specifics of how the joint is actually joined. Manners of making such a joint as is depicted in Figure 8 of Noone include using adhesives and welding. Adhesives, of course, do not require one segment to melt and another segment to remain solid. Welding usually requires some localized melting of both segments. Appellant cannot recall a method of attaching a distal tip to a catheter by melting the distal tip, and in any case, neither Noone et al. nor Wilson teach the desirability of making such a connection by melting. Noone et al., as described above, do not teach the specifics of how distal tip 45 is attached, but do not suggest or imply that it is by melting. Wilson et al. teach a distal tip 118, but this distal tip is not “a second polymer segment secured over the braid layer” as required by the language in claim 1, but is rather a reflowed section of a polymer section that is secured to the braid layer prior to cutting through the braid layer. See Wilson, 9:4-10. For at least these reasons, Appellant asserts that the prior art references do not suggest the desirability of the invention of claim 2 and submit that at least for this reason that a suggestion or motivation to modify the references is lacking, and that no *prima facie* case of obviousness has been established.

Claim 3 recites “wherein securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the

first polymer segment.” The Examiner suggests that this is modification of Noone et al. that would be obvious in view of Wilson because “it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Wilson’s heat shrink tube during Noone’s method in order to most efficiently bond the materials together.” Page 6. However, Wilson does not suggest that its method of using shrink tubing is the most efficient or even that it is efficient, merely that it is preferable for unspecified reasons for producing the catheter of Wilson. Further, Noone et al. teach a continuous extrusion process by which the various polymer layers are secured to the catheter. See Noone et al. 11:36-12:9. A catheter section can be cut from this continuous catheter body tubing and a discrete distal soft tip 45 can then be attached thereto. 12:54-55. This process of forming the continuous catheter body tubing appears to be able to be made largely automatic. Thus Appellant is unable to see why one might modify the process of Noone et al. in view of Wilson. For at least this reason, Appellant submits that there is no motivation or suggestion to modify Noone et al. in view of Wilson and that a *prima facie* case of obviousness has not been made.

Claim 4 recites, “wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer segment.” For the reasons discussed above with respect to claim 3, Appellant submits that there is no motivation to modify Noone et al. in view of Wilson to arrive at this claimed invention and, consequently, that a *prima facie* case of obviousness has not been made.

2. *All claim limitations must be taught or suggested by the prior art*

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). All of the claims rejected as obvious over Noone et al. in view of Wilson depend from claim 1, which as pointed out above is not anticipated by Noone et al. as argued by the Examiner. At least the element of “subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position,” which was not taught by Noone et al. is likewise not taught by Wilson. As discussed above, after cutting the distal tip, Wilson teaches reflowing a pre-secured polymer segment rather than securing a second

polymer segment over the braid layer. 9:4-10. Therefore, claims 2-5, 7 and 9-10 are also allowable for at least the reason that Noone et al. in view of Wilson does not teach or suggest all the claim limitations.

C. *Claim 6 is patentable over Noone et al. in view of Wilson, further in view of Zadno-Azizi (U.S. Publication No. 2004/0015150) under 35 U.S.C. § 103(a)*

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Claim 6 depends indirectly from claim 1, which as pointed out above is not anticipated by Noone et al. as argued by the Examiner. As pointed out above with respect to claims 2-5, 7 and 9-10, at least the element of “subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position,” which was not taught by Noone et al. is likewise not taught by Wilson. Appellant asserts that this element is not taught by Zadno-Azizi either. (Paragraphs 0100-0107 are most on point.) Therefore, claim 6 is allowable for at least the reason that the cited prior art does not teach or suggest all the claim limitations. Claim 6 depends directly from claim 4, and is also allowable for the reasons discussed above with respect to claim 4.

D. *Claim 8 is patentable over Noone et al. in view of Ashiya et al. (U.S. Patent No. 5,947,925) under 35 U.S.C. § 103(a)*

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Claim 8 depends from claim 1, which as pointed out above is not anticipated by Noone et al. as argued by the Examiner. As previously discussed, at least the element of “subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position,” is not taught by Noone et al. Appellant asserts that this element is not taught by Ashiya et al. either. For example, Ashiya et al. do not teach a braid layer. Therefore, claim 8 is allowable for at least the reason that the cited prior art does not teach or suggest all the claim limitations.

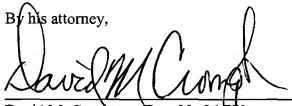
E. *Conclusion*

For at least the reasons stated above, claims 1, 11, 13, and 35-41 are not anticipated by Noone et al, claims 2-5, 7 and 9-10 are not obvious over Noone et al. in view of Wilson, claim 6 is not obvious over Noone et al. in view of Wilson and Zadno-Azizi, claim 8 is not obvious over Noone et al. in view of Ashiya et al., and the Examiner's rejections of claims these claims under 35 U.S.C. §§ 102 and 103 should be overruled.

Respectfully submitted,

Pu Zhou

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3/28/07

VIII. CLAIMS APPENDIX

1. A method of forming a catheter, comprising:

providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer;

securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end;

cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position; and

subsequent to cutting through the braid layer and the inner lubricious liner, securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position.

2. The method of claim 1, wherein the first polymer segment has a melting point that is at least about 10° F above a melting point of the second polymer segment.

3. The method of claim 1, wherein securing the first polymer segment comprises positioning a heat shrink tube over the first polymer segment and applying sufficient heat and pressure to melt the first polymer segment.

4. The method of claim 1, wherein securing the second polymer segment comprises positioning a heat shrink tube over the second polymer segment and applying sufficient heat and pressure to melt the second polymer segment but not enough heat to melt the first polymer segment.

5. The method of claim 4, wherein the first polymer segment has a melting point that is greater than about 400° F and the second polymer segment has a melting point that is less than about 400° F.

6. The method of claim 4, wherein the second polymer segment has a melting point that is about 350° F.

7. The method of claim 1, wherein the first polymer segment comprises a polyether-ester elastomer.

8. The method of claim 1, wherein the second polymer segment comprises a acetal resin/polyurethane blend.

9. The method of claim 3, wherein the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer.

10. The method of claim 4, wherein the heat shrink tube comprises a perfluoro (ethylene-propylene) copolymer.

11. The method of claim 1, wherein the second polymer segment comprises in combination a proximal segment configured to overlay the braid layer, an intermediate segment configured to overlay the first polymer segment, and a distal segment configured to form a distal tip.

13. The method of claim 1, wherein providing the braid layer comprises providing a braid layer that extends sufficiently distally of the cutting position to substantially prevent braid flaring at the cutting position.

35. A method of forming a catheter, comprising:
cutting a catheter sub-assembly at a cutting location, the sub-assembly having proximal and distal ends, an inner layer, a reinforcement layer disposed on the inner layer, and a securement layer disposed over at least a portion of the reinforcement layer;
removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location; and

subsequent to removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment extends distally of the cutting location.

36. The method of claim 35, further comprising forming a portion of the polymeric outer segment into a distal tip for the catheter.

37. The method of claim 35, further comprising assembling the catheter sub-assembly by:

providing an inner sub-assembly having the reinforcement layer disposed on the inner layer; and

disposing the securement layer on the inner sub-assembly by securing a securement segment thereon.

38. The method of claim 37, wherein:
the reinforcement layer has a distal end;
the securement segment has a distal end; and
the step of disposing the securement layer on the inner sub-assembly is performed such that the distal end of the reinforcement layer extends distally beyond the distal end of the securement segment.

39. The method of claim 35, wherein the reinforcement layer comprises a braided member.

40. A method of forming a catheter, comprising:
providing a braid layer having a distal end and a proximal end;
positioning an inner lubricious liner within the braid layer;
securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer;
cutting through the braid layer at a cutting location proximal of the distal end of the braid layer, thereby forming a catheter sub-assembly including the inner lubricious liner, the braid layer,

and the first polymer segment, the catheter sub-assembly having a distal end defined at the cutting location; and

securing a second polymer segment over the catheter sub-assembly, the second polymer segment extending over the first polymer segment of the catheter sub-assembly and extending distally of the distal end of the catheter sub-assembly;

wherein the step of securing the second polymer segment over the catheter sub-assembly is performed subsequent to the step of cutting through the braid layer.

41. The method of claim 40, wherein the first polymer segment prevents flaring of the braid layer consequent cutting through the braid layer.

IX. EVIDENCE APPENDIX

There is no evidence.

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals or interferences.